

## Food and Drug Administration, HHS

## § 880.3

- 880.6300 Implantable radiofrequency transponder system for patient identification and health information.
- 880.6310 Medical device data system.
- 880.6315 Remote medication management system.
- 880.6320 AC-powered medical examination light.
- 880.6350 Battery-powered medical examination light.
- 880.6375 Patient lubricant.
- 880.6430 Liquid medication dispenser.
- 880.6450 Skin pressure protectors.
- 880.6500 Medical ultraviolet air purifier.
- 880.6710 Medical ultraviolet water purifier.
- 880.6730 Body waste receptacle.
- 880.6740 Vacuum-powered body fluid suction apparatus.
- 880.6760 Protective restraint.
- 880.6775 Powered patient transfer device.
- 880.6785 Manual patient transfer device.
- 880.6800 Washers for body waste receptacles.
- 880.6820 Medical disposable scissors.
- 880.6850 Sterilization wrap.
- 880.6860 Ethylene oxide gas sterilizer.
- 880.6870 Dry-heat sterilizer.
- 880.6880 Steam sterilizer.
- 880.6885 Liquid chemical sterilants/high level disinfectants.
- 880.6890 General purpose disinfectants.
- 880.6900 Hand-carried stretcher.
- 880.6910 Wheeled stretcher.
- 880.6920 Syringe needle introducer.
- 880.6960 Irrigating syringe.
- 880.6970 Liquid crystal vein locator.
- 880.6980 Vein stabilizer.
- 880.6990 Infusion stand.
- 880.6991 Medical washer.
- 880.6992 Medical washer-disinfector.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 69682, Oct. 21, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 880 appear at 73 FR 35341, June 23, 2008.

### Subpart A—General Provisions

#### § 880.1 Scope.

(a) This part sets forth the classification of general hospital and personal use devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in

this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a general hospital and personal use device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17738, May 11, 1987, as amended at 69 FR 71704, Dec. 8, 2004]

#### § 880.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class